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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/840,238 | 05/07/2004 | David Loakes | 056222-5030-01 | 7610 |

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

| EXAMINER | |
|---|---|
| WANG, SHENGJUN | |
| ART UNIT | PAPER NUMBER |
| 1617 | |
| MAIL DATE | DELIVERY MODE |
| 11/13/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/840,238 | LOAKES ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,17-20,24,25,27,29,30,32-34 and 37* is/are pending in the application.

4a) Of the above claim(s) *10,11,24,25,27,34 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12-14,17-20,29,30,32,33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 28, 2008 is acknowledged.

### *Claim Objections*

1. Claim 14 is objected to because of the following informalities: it is inform to recite a compound by referring to the specification. It is suggested to include the formula in the claims, or recite its chemical name. Appropriate correction is required.

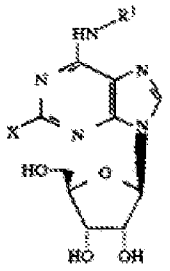
### *Claim Rejections 35 U.S.C. 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-9, 12-14, 17, 29, 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntsen et al. (US 5,430,027).

4. Kuntsen et al. teaches 2, N6 substituted adenosine, their pharmaceutical compositions, and activity in treating ischemias. Kuntsen et al. disclose the general formula of the substituted adenosine as follow



Wherein X may be amino, and R1 is Y-R4, wherein Y may be oxygen and R4 C1-6 alkyl. See, particularly, the abstract, column 3, line 24, to column 4, line 18. The compounds may be formulated into a variety of pharmaceutical dosage with conventional adjuvant, carrier, or diluent, wherein the amounts of the compound may be in the range of 10 to 100 mg. See, particularly, col. 7, line 65 to col. 9, line 15. Kuntsen et al. disclose the employment of polyhydroxylated castor oil as carrier (col. 8, lines 58-61), meet the limitation of surfactant recited in claims 33. Note the amounts disclosed by Kuntsen et al. would meet the limitation of "effective amount" defined in this application (see page 10 of the specification herein).

Kuntsen et al. do not teach expressly the particular compound elected herein. However, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to make 2-amino, N6-methoxy adenosine and use the same for making pharmaceutical composition for treatment of ischemias because the 2, 6 substituted adenosine, such as those with 2-amino, and 6-methoxy, are known to be similarly useful to other 2, 6-substituted adenosine. The employment of additional 2, 6-substituted adenosine within a composition would have been obvious as they are disclosed as similarly useful. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art.

See In re Kerkhoven, 205 USPQ 1069. Further, the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161. Furthermore, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

5. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntsen et al. (US 5,430,027), for reasons set forth above, in further view of Puglieses.

6. Kuntsen et al. do not teach expressly the further incorporation of an antiviral agents, such as those used for treatment of HIV.

7. However, Puglieses et al. teaches that HIV patient who take nucleoside reverse transcriptase inhibitor have high incidence of cardiac ischemia. See, particularly, the results at page 283.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further incorporate the adenosine derivatives herein in a NRTI pharmaceutical composition for HIV patients who developed cardiac ischemia. A person of ordinary skill in the art would have been motivated to further incorporate the adenosine derivatives herein in a NRTI pharmaceutical composition for HIV patients who developed cardiac ischemia because the adenosine derivatives herein are known to treat cardiac ischemia.

***Response to the Arguments***

Applicants' amendments and remarks submitted July 28, 2008 have been fully considered, but are not persuasive as to the rejections set forth above.

Applicants' arguments are moot in view of the new ground of rejections. Particularly, Kuntsen et al. discloses a unit dosage contains 10 to 100 mg of the active compound. Further, since the claims are drawn to a composition, there is no limitation as to the percentage of the active ingredients in the composition, Kuntsen's dosage form would meet the limitation herein.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617